K122445

GE Healthcare

Datex-Ohmeda Inc.
3030 Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550
USA

OCT 12 2012

Premarket Notification 510(k) Summary
As required by section 807.92
GE Datex-Ohmeda Aespire Anesthesia System

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)
COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
Datex-Ohmeda, Inc..
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2132

NAME OF CONTACT:

Mr. James P. Raskob
Ms. Monica Morrison (alternate)

DATE:

October 12, 2012

DEVICE NAME as required by 807.92(a)(2)
TRADE NAME:

GE Datex-Ohmeda Aespire Anesthesia System

COMMON NAME:

Gas Machine, Anesthesia

CLASSIFICATION NAME:

Anesthesiology, 73 BSZ, 21 CFR 868.5160 Gas Machine, Anesthesia

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The GE Datex-Ohmeda Aespire 7900 and Aespire View products are considered substantially equivalent to, and as safe and effective as, the legally marketed (predicate) GE Datex-Ohmeda Aespire 7900, Aespire View (K092864).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The systems are to be used only by trained and qualified medical professionals.

The Aespire 7900 and Aespire View supply set flows of medical gases to the breathing system. A large selection of frames, gases, and vaporizers are available to give the user control of the system configuration. They are available in trolley and pendant models, with two or three gases, two vaporizer positions and up to three cylinder connections. All models connect to oxygen and can additionally connect with up to two optional gases (air, N2O). The Aespire systems accept Tec 4, Tec 5, Tec 6, Tec 6+ and Tec 7 vaporizers on a Selectatec manifold. Safety features are designed to decrease the risk of hypoxic mixtures, agent mixtures and complete power or sudden gas supply failures. The Aespire View product provides optional electronic Total Fresh Gas Flow (TFS) monitoring. The Aespire View also features a color display, while the Aespire 7900 uses a monochromatic display.

The Datex-Ohmeda 7900 Anesthesia Ventilator is used in this family of Anesthesia Systems. It is a microprocessor based, electronically controlled, pneumatically driven ventilator that provides patient ventilation during surgical procedures. The 7900 ventilator is equipped with a built-in monitoring system for inspired oxygen, airway pressure and exhaled volume. Sensors in the breathing circuit are used to control and monitor patient ventilation as well as measure inspired oxygen concentration. This allows for the compensation of compression losses, fresh gas contribution and small leakage in the breathing absorber, bellows and system. User setting and microprocessor calculations control breathing patterns. The user interface keeps settings in memory. The user may change settings with a simple and secure setting sequence. A bellows contains breathing gasses to be delivered to the patient. Positive End Expiratory Pressure (PEEP) is regulated electronically. Positive pressure is maintained in the breathing system so that any leakage that occurs is outward. An RS-232 serial digital communications port connects to and communicates with external devices. Ventilator modes for the device include Volume Control (VCV) Mode, Pressure Control (PCV) Mode (Optional), Synchronized Intermittent Mandatory Ventilation with Pressure Support Ventilation (SIMV/PSV) Mode, Pressure Support with Apnea Backup (PSVPro) Mode (Optional), Synchronized Intermittent Mandatory Ventilation with Pressure Control (SIMV-PC) Mode (Optional), and Pressure Control Ventilation – Volume Guaranteed (PCV-VG) mode (Optional on Aespire View variant only).

INTENDED USE as required by 807.92(a)(5)

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The devices are intended for volume or pressure control ventilation.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The GE Datex-Ohmeda Aespire 7900 and Aespire View have been updated from the predicate version (K092864). There have been no changes to the intended use or fundamental scientific technology.

The electronic sensor interface circuit board used within the Aespire 7900 and Aespire View has been updated. The primary change included replacement of a mechanical switch for airway overpressure detection with an electronic monitoring circuit for airway overpressure detection. The existing mechanical overpressure relief valve that serves as an additional safety mitigation remains unchanged.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The GE Datex-Ohmeda Aespire 7900 and Aespire View Anesthesia Systems have been thoroughly tested through verification of specifications. The following quality assurance measures were applied to the development of the revised circuit board:

- Risk Analysis
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)

Verification tests completed during the development process included environmental verification testing and electromagnetic compatibility verification testing.

SUMMARY OF CLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(2)

The modification to the family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator did not require clinical testing.

CONCLUSION:

GE Healthcare considers the GE Datex-Ohmeda Aespire 7900 and Aespire View anesthesia machines to be as safe, as effective, and have performance substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 12 2012

Mr. James P. Raskob
Regulatory Affairs Leader
GE Healthcare
Datex-Ohmeda, Incorporated
3030 Ohmeda Drive
P.O. Box 7550
Madison, Wisconsin 53707-7550

Re: K122445
Trade/Device Name: GE Datex-Ohmeda Aespire Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 12, 2012
Received: September 13, 2012

Dear Mr. Raskob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

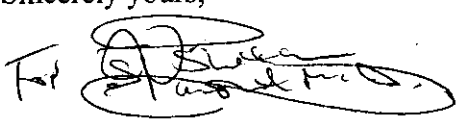
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: GE Datex-Ohmeda Aespire Anesthesia System

Indications For Use:

The family of GE Datex-Ohmeda Aespire anesthesia systems with 7900 ventilator (Aespire 7900 and Aespire View) is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients. The devices are intended for volume or pressure control ventilation.

Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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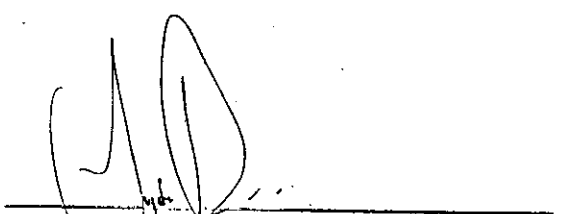
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122445